### REMARKS

Reconsideration and reexamination of this application are respectfully requested.

Applicant courteously acknowledges receipt by the Office of the Deposit Declaration filed August 9, 2007.

Applicant respectfully disagrees with the Examiner's statement that "Applicant has not relied on the benefit of foreign priority." (Office Action at ¶ 3.) As indicated in the documents attached hereto and incorporated herein, Applicant claimed priority "based on Canadian Application Nos. 2,345,206, filed May 16, 2001 and 2,346,968, filed May 23, 2001." (See attached Cover Letter dated November 14, 2003, at p. 2). The PCT attached to the cover letter contained the same information. (See PCT WO 02/092628 cover page, attached for convenience.) Furthermore, the PTO received this information, as indicated by the return postcard, which is also attached. Accordingly, Applicant has relied on the benefit of foreign priority, thereby setting May, 16, 2001, as the earliest priority date for this application.

Claims 4, 5, 8-11, and 42 are pending.

• • •

Claims 2-3, 6-7, and 41 are canceled.

Claims 1, 12-40, 43, and 44 are withdrawn.

Claims 4 and 5 are amended. Support for these amendments appears in the following representative passages of the application: claim 4 - Spec. at [0012], and claim 5 - Spec. at [0012].

Claims 45 and 46 are new. Support for these claims appears in the following representative passages of the application: claim 45 - claim 4, and claim 46 - claim 5.

Reply to Office Action

Application Serial No.: 10/712,533

New Attorney Docket No.: 03495.0380-00000

Rejection Under 35 U.S.C. § 102(b)

The Examiner rejected Claims 4, 5, 8, 9, and 42 under 35 U.S.C. § 102(b) as being anticipated by Gardner et al., 282 Science 1126 (1998). (Office Action at ¶ 9.) The Examiner argues that the specification defines the "peptide sequence" of the claimed invention as at least 5 amino acids in length. (Office Action at 5.) The Examiner interprets Applicant's claims as reading on a peptide sequence of as few as 5 amino acids. (Id.) The Examiner continues by noting that the cited reference discloses peptides of at least 5 amino acids in length that are identical to Applicant's claimed invention. (See id. at 5-6.) Accordingly, the Examiner concluded that the cited reference would thereby anticipate the claimed invention as defined by the specification. (Id.)

Without agreeing with the Examiner's claim construction, Applicant has amended the disputed claims. Claim 4 is amended to remove "peptide sequence" and recite "[a]n isolated polypeptide consisting of SEQ ID NO: 3 (DG747)." Claim 5 is amended to remove "peptide sequence" and recite "polypeptide having 95% identity with the sequence as claimed in claim 4." The remaining claims depend from claims 4 and 5, thereby importing these limitations by reference. Gardner fails to disclose these limitations of the claimed invention either directly or inherently. Given that Gardner fails this test, it cannot anticipate claims 4, 5, 8, 9, and 42 under 35 U.S.C. § 102(b). Thus, the claims are allowable.

Rejection Under 35 U.S.C. § 103

Application Serial No.: 10/712,533

New Attorney Docket No.: 03495.0380-00000

The Examiner rejected claims 10 and 11 under 35 U.S.C. § 103(a) as obvious in light of Gardner *et al.* combined with Druilhe *et al.*, (U.S. Patent No. 6,191,270). In particular, the Examiner contends that Gardner *et al.* "teaches the claimed invention except for the recitation of the support." (Office Action at ¶ 10.) The Examiner further argues that Druilhe *et al.* "teaches use of isolated and purified polypeptides from *P. falciparum*" and "that the antigens or peptides according to the invention may be coupled to traditional supports or adsorbed on such supports." (*Id.*) Applicant respectfully traverses.

"Obviousness is a question of law based on underlying factual inquiries," which include: the scope and content of the prior art; the differences between the claimed invention and the prior art; and a determination of the level of ordinary skill in the pertinent art. MPEP § 2141, 8th ed., 6th rev. (Sept. 2007). The Office bears the initial burden of factually supporting a *prima facie* conclusion of obviousness. MPEP § 2142. The analysis supporting a rejection under 35 U.S.C. § 103(a) should be made explicit by clearly articulating the reason why the claimed invention would have been obvious. *Id.* The Federal Circuit has stated that "rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)); *see also KSR Int'I Co. v. Teleflex Inc.*, 82 U.S.P.Q. 2d 1385, 1396 (2007) (quoting Federal Circuit statement with approval). In addition, when conducting an obviousness analysis, "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from

Reply to Office Action

Application Serial No.: 10/712,533

New Attorney Docket No.: 03495.0380-00000

the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984)." M.P.E.P. § 214.03.

Applicant respectfully submits that the cited prior art fails to disclose all of the limitations of the claimed invention. Moreover, the Examiner does not account for these differences or indicate how the cited reference combination overcomes them. The claimed invention recites a specific amino acid sequence; polypeptides containing at least 40 consecutive amino acids identical to that sequence; or a polypeptide having 95% identity with that sequence.

Gardner *et al.*, meanwhile, discloses only a <u>predicted</u> protein sequence, and as noted by the Examiner, one possessing less than 92% identity with the claimed invention. (Office Action at 4.) Notably, the sequence (PFB0155c) is one of 209 appearing in the reference and only as a small notation in a single Figure. *See* Gardner *et al.* at Fig. 1. Absent from the reference is an indication that any of the predicted sequences actually encodes a polypeptide, whether such a polypeptide would fold correctly if expressed, or whether such a polypeptide would induce an immune response. Further, the reference actually shows that the authors recognized they were only making conjectures. *See* Gardner, *et al.* at 1126-1127 (stating that "[o]f the 209 protein-encoding genes, 43% contain at least one intron," and "[t]his percentage is an <u>estimate</u>, because <u>some introns may have been missed</u> by the gene finding method"). In view of such deficiencies, the reference discloses insufficient information for a person of ordinary skill to reasonably succeed in practicing the claimed invention.

Reply to Office Action

Application Serial No.: 10/712,533

New Attorney Docket No.: 03495.0380-00000

Combining Gardner et al. with Druilhe et al. fails to address any of the aforementioned problems. As noted by the Office, Druilhe et al. teaches the use of isolated and purified polypeptides from P. falciparum. However, it does not teach whether the PFB0155c sequence of Gardner et al. encodes any polypeptide, let alone

an immunogenic polypeptide, or even the polypeptides of the claimed invention.

Considering the information listed above, the Office has not presented a prima facie case that claims 10 and 11 are obvious under 35 U.S.C. § 103(a) in view of Gardner et al. combined with Druilhe et al. Thus, these claims are allowable.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Kenneth J. Mevers

Reg. No. 25,146 Tel.: 202 408-4033

Dated: February 11, 2008

Conclusion

Attachments: Transmittal Letter

Cover page for WO 02/092628 Postcard received from the PTO

# (12) DEMANDE INTERNATIONALE PUBLIÉE EN VERTU DU TRAITÉ DE COOPÉRATION EN MATIÈRE DE BREVETS (PCT)

#### (19) Organisation Mondiale de la Propriété Intellectuelle

Bureau international



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2.345,206 16 mai 2001 (16.05.2001) CA 2.346,968 23 mai 2001 (23.05.2001) CA

- (71) Déposant (pour tous les États désignés sauf US): IN-STITUT PASTEUR [FR/FR]; 25-28, rue du Dr. Roux, F-75724 Paris Cedex 15 (FR).
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(81) États désignés (national): AE. AG. AL. AM. AT. AU. AZ. BA, BB, BG, BR, BY, BZ. CA. CH. CN. CO, CR. CU, CZ. DE, DK. DM, DZ. EC. EE, ES, FI. GB. GD, GE. GH, GM. HR, HU, ID, IL, IN, IS, JP, KE. KG, KP. KR, KZ. LC, LK. LR, LS. LT, LU, LV, MA, MD, MG. MK. MN, MW, MX. MZ. NO, NZ, OM, PH, PL. PT. RO. RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) États désignés (régional): brevet ARIPO (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ. UG, ZM. ZW), brevet eurasien (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), brevet européen (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), brevet OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

#### Publiée:

 sans rapport de recherche internationale, sera republiée dès réception de ce rapport

En ce qui concerne les codes à deux lettres et autres abréviations, se réfèrer aux "Notes explicatives relatives aux codes et abréviations" figurant au début de chaque numéro ordinaire de la Gazette du PCT.

(54) Title: PLASMODIUM FALCIPARUM ANTIGENS AND VACCINE AND DIAGNOSTIC USES THEREOF

(54) Titre: ANTIGENES DE PLASMODIUM FALCIPARUM ET LEURS APPLICATIONS VACCINALES ET DIAGNOSTIQUES

(57) Abstract: The invention concerns novel *Plasmodium falciparum* antigens and their vaccine and diagnostic applications. More particularly, the invention concerns immunogenic polynucleotide and polypeptide molecules, compositions comprising them, and methods for diagnosis and vaccination of malaria.

(57) Abrégé: La présente invention se rapporte à de nouveaux antigènes de Plasmodium falciparum et à leurs applications vaccinales et diagnostiques. Plus particulièrement, la présente invention vise des molécules polynucléotidiques et polypeptidiques immunogéniques, des compositions les comprenant, et des méthodes de diagnostic et de vaccination du paludisme (malaria).



# PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:

New U.S. Application for:

PLASMODIUM FALCIPARUM ANTIGANS AND VACCINE AND DIAGNOSTIC USES THEREOF

being a Continuation of International Application No. PCT/FR02/01637 filed May 15, 2002

Inventors: Pierre DRUILHE and Anne-Charlotte GRÜNER

## MAIL STOP PATENT APPLICATION

- 1. Check for \$1148.00
- 2. Transmittal Letter
- 3. French Language Spec. 62 pgs. with at least 1 indep. clm. and 41 clms. total
- 4. Drawings 28 sheets of drawings containing 15 figures
- 5. Cover page for International Publication No. WO 02/092628 A2

Dated November 14, 2003

Docket No.: 02356.0086

CUSTOMER NUMBER: 22,852 EFC/FPD/gah Mail Drop 360 e Date: November 16, 2003)

IIIs/03 JO



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November 14, 2003

ATTORNEY DOCKET NO.: 02356.0086 CUSTOMER NUMBER: 22,852

MAIL STOP PATENT APPLICATION Assistant Commissioner for Patents Washington, D.C. 20231

New U.S. Patent Application

Title: PLASMODIUM FALCIPARUM ANTIGANS AND VACCINE AND DIAGNOSTIC USES THEREOF being a Continuation of PCT International Application No. PCT/FR02/01637 filed May 15, 2002 Inventors' Names and Residences:

- 1) Pierre DRUILHE Paris, France
- 2) Anne-Charlotte GRÜNER Paris, France

#### Dear Sir:

We enclose the following papers for filing in the United States Patent and Trademark Office under 35 U.S.C. 111(a) as a **Continuation** application of PCT International Application No. PCT/FR02/01637 filed May 15, 2002 which claimed priority of Canadian Patent Application Nos. 2,345,206, filed May 16, 2001; and 2,346,968, filed May 23, 2001.

The application, which is not in the English language is enclosed, for filing in the United States Patent and Trademark Office in connection with the above-referenced application in accordance with 37 C.F.R §1.52(d) and §808.01 of the MPEP, Filing of Non-English Language Applications:

- 1. Non-English/Application 62 pages, including at least 1 independent claim and 41 claims total.
- 2. Drawings 28 sheets of formal drawings containing 15 figures.

- 3. Sequence Listing consisting of 24 pages in written form
- 4. The filing fee is calculated as follows:

Basic Application Filing Fee					\$770		\$770.00
	Number of Claims		Basic	Extra Claims			
Total Claims	41	-	20	21	x \$18		378.00
Independent Claims	1	-	3		x \$86		· · · · · · · · · · · · · · · · · · ·
☐ Presentation of Multiple Dep. Claim(s) +\$290							
Subtotal						\$	1148.00
Reduction by ½ if small entity						-	
TOTAL APPLICATION FILING FEE						\$	1148.00

5. A check for \$1148.00 is enclosed. The fee includes:

\$770.00 filing fee; and

\$378.00 additional claims fee.

Applicants claim the right to priority based on Canadian Application Nos. 2,345,206, filed May 16, 2001; and 2,346,968, filed May 23, 2001.

This application is being filed under the provisions of 37 C.F.R. § 1.53(f). Applicants await notification from the Patent and Trademark Office of the time set for filing the Declaration.

An English translation of the non-English language papers will be filed in the U.S. Patent and Trademark Office within the required time period.

Please address all correspondence with respect to this application to:

Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 1300 I Street, N.W. Washington, D.C. 20005-3315

Please accord this application a serial number and filing date.

Commissioner for Pate November 14, 2003 Page 3

FINNEGAN HENDERSON FARABOW GARRETT & DUNNER

The Commissioner is hereby authorized to charge any additional filing fees due and any other fees due under 37 C.F.R. § 1.16 or § 1.17 during the pendency of this application to our Deposit Account No. 06-0916.

Sincerely,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By:

Ernest F. Chapman

Reg. No. 25,961

EFC/gah Enclosures